BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

ANNUAL CONFERENCE

June 06, 2024 | Annual Congress of BADI 2024 – Pharmaceutical Legislation – Update

Venue: University Hospital "St. Ekaterina" | Aula "Prof. Dr. Alexandar Chirkov", Sofia

Event for experts in the pharmaceutical sector and competent authorities

SPEAKERS

For more information – www.badibg.org / office@badibg.org

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Prof. Dr. rer. nat. Barbara Sickmüller is a pharmacist. She studied and obtained her doctorate at the Philipps University in Marburg - Germany (1967-1974).

From 1977 she worked as a scientific executive at the Association of the German Pharmaceutical Industry (BPI) and took over the section "Drug Safety" of BPI in 1979. 1984/1985 she had a sabbatical year in the USA with training into US drug legislation. From 1988 she was appointed as head of the department "Medical affairs" and from 1997 Director of the Medicines and Pharmacy Division of BPI. In 2000 she was appointed as Deputy Director General of BPI.

Since 1987 until 2011 she gave yearly lectures in the department of Pharmacy, University of Marburg, and was appointed honorary Professor of the University of Marburg/Lahn (Januar 2000). In addition, she gave lectures for the Master of Drug Regulatory Affairs at the University in Bonn. She had further teaching assignments at the Universities of Frankfurt and Heidelberg on Pharmacovigilance and clinical trials, and has published numerous publications and book contributions in these regulatory areas.

The German Ministry of Health appointed her as Member of the Advisory Committee on prescription of pharmaceutical products, the Commission on Medicines for Children and Adolescents (KAKJ) and member of the Board of Trustees of the Institute for Quality and Efficiency in Health Care (IQWiG) and a member of the Board of Trustees of the German Agency for Health Technology Assessment (HTA) at DIMDI.

She was member of several Working Groups of the Council for International Organizations of Medical Sciences (CIOMS) and the International Council for Harmonization of Marketing Authorization Requirements (ICH) in the areas of pharmacovigilance and clinical trials.

Since March 2012 she has retired and is now active as Senior Scientific Advisor for BPI. Furthermore,she gives lectures on Pharmacovigilance and clinical trials at the Universities in Bonn, Heidelberg and Marburg.

In July 2014 she was appointed President of the German Association for Regulatory Affairs (DGRA)in Bonn and in October 2014 as member of the university council of the University of Applied Sciences of Central Hesse (THM) in Gießen.

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Dr. Birka Lehmann
Senior Expert Drug Regulatory Affairs

Birka Lehmann studied Medicines at the Free University Berlin and trained at the Kinderklinik Norderney. Her working experience includes 9 years preclinical assessment in the division 'Pharmacology and Toxicology' of BfArM and she served as head of unit 'Decentralised Procedure' (1996-2002) and as deputy head of EU Division (2000-2002). She was member of and chaired the Mututal Recognition Facilitation Group and served as expert to the Committee for Human Medicinal Products (EMA).

From 2002 – 2006 she joined the European Commission, Directorate-General Enterprise and Industry as expert on secondment to in the unit 'Pharmaceuticals' responsible for inter alia Marketing Authorisation and implementation of Clinical Trials Directive.

From September 2006 till October 2011 she was head of the division 3 Marketing Authorisation procedure at the BfArM compromising several indication areas including cardiovascular and pulmonary disease, antibiotics and dermatology.

She was head of Executive Department EU and International Affairs of the Federal Institute for Drugs and Medical Devices (BfArM) from October 2011 till end of 2015. She was member of the Paediatric Committee at the European Medicines Agency from 2007 till 2016.

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Dr. Christa Wirthumer-Hoche
Former Head of the Austrian Medicines and Medical Device Agency at AGES - Former Chair of the EMA Management Board

DI Dr. Christa Wirthumer-Hoche studied biochemistry at the Technical University in Vienna and did her doctoral thesis at the Institute of Medical Physiology in 1983.

First at the Austrian Institute for Drug Control (1983 - 1998), her area of responsibility was the quality assessment of medicinal products, and from 1998 at the Federal Ministry of Health and Women's Affairs, she was Head of the Marketing Authorisation Department for Medicinal Products.

Since the founding of the new Austrian agency on 1 January 2006, she has been Head of the Institute for Market Authorisation and Lifecycle Management of Medicinal Products. Since October 2013, she has been Head of the Austrian Agency for Medicinal Products and Medical Devices at AGES (Austrian Agency for Health & Food Safety), and a leading member of BASG (Federal Office for Safety in Health Care).

Since 1994, she has been a member of several European committees and working groups, and was elected Chair of the EMA (European Medicines Agency) Management Board from March 2016 – March 2022.

As a guest lecturer, she teaches the subject "Regulatory Affairs of Medicinal Products" at several European universities.

Retired since 1 April 2023.

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Prof. Dr. Folker Spitzenberger, PhD (Molecular Biology), Chemist (Diploma), Drug Regulatory Affairs (Master, MDRA), Fachhochschule Lübeck, University of Applied Sciences, Focus area of clinical/scientific work. Drug and medical device regulatory affairs, standardization, quality management, conformity, assessment, accreditation, laboratory medicine, in vitro diagnostic medical devices ; Experience in international projects. Since 2005 until present experience as consultant, scientific expert, advisor for WHO, EU, PTB and other organizations in numerous international projects related to regulatory affairs, quality assurance, quality management, biosafety/biosecurity, accreditation/certification and standardization of medical/health laboratories. Membership of Scientific Societies /Relevant Professional Bodies

1. ISO TC 212: „Clinical laboratory testing and in vitro diagnostic test systems“
2. CEN TC 140 „Clinical laboratory testing and in vitro diagnostic test systems“
3. German Standards Committee DIN NAMed „Quality Management in medical laboratories“ with the following functions: 1. Member and Chair of the German delegation; 2. Chairman of CEN TC 140 WG 3; 3. Chairman of the German standards committee. Member of the Scientific Board of DIW-MTA e. V.

Training and Education: International work experience as senior scientist, quality assessor and quality expert for all kinds of quality systems related to the: In vitro diagnostic medical devices (IVDMD) sector including branches as accreditation and designation (German Accreditation Body DAkkS; Central Authority of the Laender for health protection regarding medicinal products and medical devices ZLG); Certification and GMP (International projects for WHO, EU and others); risk assessment and vigilance (Paul-Ehrlich-Institute PEI); Disease control and prevention (Robert Koch-Institute RKI).

Numerous publications and projects in the field of quality assurance/quality management,
Standardization and regulatory affairs related to the IVDMD sector.

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CELEBRATING 10 YEARS ANNIVERSARY

Ekaterina Genova is a Doctor of Medicine, holding a degree from the Medical University of Sofia. She specialized in Ophthalmology and Neuro-ophthalmology. Dr Ekaterina Genova is a member of the Bulgarian Medical Association since 1999. After several successful years in the Military Medical Academy of Sofia, she joined the pharmaceutical industry, the German company Asta Medica in 1999.

Ekaterina Genova has a long and successful career in the healthcare and pharma industries through which she built an extensive network across the Bulgarian and Eurasian Markets. Since 2007 she has been responsible for the Business Development and Growth of Ecopharm - initiating cooperation with potential partners and building the product portfolio of the company. In 2014 Ekaterina took a year-long course at the Pharmaceutical Faculty in Sofia, which enhanced her knowledge in disciplines such as analysis, testing, pharmaceutical chemistry and technology which helped her to understand the end-to-end process of drug manufacturing. She was leading both the Business Development and Regulatory Departments of Ecopharm, and built the pharmacovigilance department of Ecopharm, including the whole pharmacovigilance system and processes.

Since 2014, Ekaterina has been a QPPV of Ecopharm. She is legally responsible for the safety of all medical products that the company sells and also acts as a single point of contact for EMA.

Throughout the years, Ekaterina has been both a participant and a lecturer at various courses and events related to the regulation of drugs and medical devices held by BADI, EMA, DIA and as well as other organizations. In 2016 she gained a Diploma in Health Management from the Medical University of Sofia.

In 2017, after years of experience both as a doctor and a lead in the pharmaceutical industry, Ekaterina decided to set up her own consultancy company. She has been advising start-ups and working on transformational projects for other companies, focusing innovation and technology in the healthcare sector. She has the ability to build the “big picture” and be seen as a trusted advisor.

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CELEBRATING 10 YEARS ANNIVERSARY

Radoslava Naydenova – Tunel

Radoslava holds a master's degree in Strategic management of the Pharmaceutical Industry from Medical University, Sofia as well as Bachelor's degree in Linguistics and International relations from Sofia University. She has extensive experience in different areas of pharmaceutical industry gained over the last 15 years in the fields of manufacturing and importation planning, pricing and reimbursement, sales analysis, and pipeline project management.

As a Regulatory Affairs professional she has in-depth knowledge of the local Bulgarian and EU legislation procedures and guidelines governing pharmaceutical products, GMP, GDP, food supplements, medical devices, and cosmetics. For the period of 14 years starting from 2008 until beginning of 2023, she has taken different expert and management positions at Nobel Pharma Bulgaria, last of which Regulatory Affairs Project manager.

Since February 2023 she has joined the pharmaceutical consultancy field as a Senior Manager Regulatory Affairs at PharmaLex with broad span of regulatory interactions with EMA, CMDh and EU national competent health authorities as well as Swissmedic.

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Daniela Cherneva, PhD

Daniela Cherneva graduated from Sofia University "St. Kliment Ohridski" in 2008 with a Bachelor's degree in Russian philology. In 2011 she graduated from New Bulgarian University in Sofia with Master's degree in International Business and in June 2015 she obtained a Master's degree in Public Health and Healthcare Management from the Faculty of Public Health of the Medical University in Sofia. In April 2021 Daniela obtained a PhD in the Faculty of Public Health, Medical University in Sofia with a dissertation on "Challenges in front of the reference pricing of generic medicines in Europe". She has 13 years of experience in the Regulatory Affairs, currently in the position of Regulatory Affairs Manager in Medochemie Ltd. Bulgaria.

During her professional life she gained broad experience not only in Regulatory Affairs, but also in pricing and reimbursement, market access, pharmacovigilance, life-cycle product management, etc. Daniela has more than 16 publications and conference participations in the field of Regulatory Affairs and is a member of the Bulgarian Association for Drug Information (BADI) and the International Society for Pharmacoeconomic and Outcome Research (ISPOR).

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Margarita Strokova, MD has master's degree in Medicine from Medical University, Sofia and Master of Business Administration from New Bulgarian University, Sofia. Joined Pharma Industry in 1997 and has extensive experience in pharmaceutical marketing, scientific communication, Medical Governance and Pharmacovigilance (for products both under clinical trials and marketed). Worked for over 13 years as local person responsible for Pharmacovigilance in GSK Bulgaria and has 3 years experience as Local Country Medical Head. In Feb 2021 joined IQVIA as Associate Manager, Safety Operations Team.

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Prof. Dobriana Sidjimova, PhD graduated Sofia University in 1998 with subject Russian Philology with a Master`s degree. In 2001 she defended Master`s degree in Public Relations at the Sofia University. In 2003 she obtained Master`s degree in Health management at the Medical University of Sofia in the Faculty of Public Health. In 2005 she defended a PhD thesis. Her professional experience started as a State Expert in the PR Department of the National Health Insurance Fund. In 2006 she became an Assistant Professor at the Faculty of Public Health in the Medical University of Sofia. Since 2008 she is an Associate Professor in The Faculty Of Public Health, Medical University, Sofia. In 2014 obtain "Health Economics" speciality. Till 14th of May 2015 she was Chairman of Board of Directors of BADI. In 2016 she became Professor at the Faculty of Public Health, MU-Sofia. She is Chief Editor of Health Policy and Management Journal. Prof. D. Sidjimova is Head of Department of Medical Pedagogy, Language and Sport in Medical University of Sofia.

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Prof. Tatyana Benisheva - Dimitrova, DSc., President of BADI is a professor in the Faculty of Public Health at Medical University, Sofia. After receiving an EC-CADREAC scholarship she completed master's degree in Drug Regulatory Affairs (2004/2005) at the University of Bonn and later in 2010 a Master degree in "Public Health" at the Medical University of Sofia, Bulgaria.
She was a Director of the "Drug Policy" Department at the Ministry of Health (2000-2005) and has over 10 years of experience at the Bulgarian Drug Agency (BDA). As the first president of the National Council on Prices and Reimbursement of Medicinal Products 2013-2014 she started an EU-project-OPAC for establishing of electronic database of medicinal product.

As a managing director of consulting in Bulgaria Betaconsult Pharma Ltd. (2007-2013) she developed activities at the global regulatory database IDRAC of the Thompson Reuters (2006-2012). She was involved like an expert in the project of the European Commission - PLAC assignment medicinal product pricing in Serbia, in 2016. Prof. Benisheva is member of DIA and DGRA and Board member of the EAMEA, Advisory council at the DIA in Europe, since 2017. Her 25 years of experience in drug regulatory affairs (life cycle management and market access of medicinal product) is complemented by more than 100 publications in the regulatory science field of medicines.